CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION
PUBLIC REPORT 2006-3

Flumiclorac-pentyl
Tracking ID Number 213271

DESCRIPTION OF ACTION

Valent U.S.A. Corporation submitted an application seeking California registration of Resource Herbicide, EPA Reg. No. 59639-82, which is a selective herbicide for post emergence control and suppression of susceptible broadleaf weeds in field corn and soybeans. Resource Herbicide contains the new active ingredient flumiclorac-pentyl.

The Department of Pesticide Regulation (DPR) evaluated the product label and data and found them acceptable to support conditional registration. Precautionary and first aid statements on the product labels, as well as label directions requiring personal protective equipment (PPE) and other protective measures adequately mitigate potential health risks to persons who may come in contact with the pesticide during application. DPR does not expect significant adverse environmental impacts to result from registration of Resource Herbicide. The U.S. Environmental Protection Agency (U.S. EPA) registered Resource Herbicide conditionally on November 18, 1994. Under the conditions of registration, acceptable residue chemistry data were required derived from flumiclorac-pentyl on soybean hay and forage. This data requirement was satisfied and Resource Herbicide is currently fully registered with U.S. EPA. However, it should be noted that because soybeans are not grown commercially in California the portion of the Resource Herbicide label pertaining to soybeans is not covered in this report.

BACKGROUND

Registrant:	Valent U.S.A. Corporation
Common name:	Flumiclorac-Pentyl Chemical name: pentyl[2-chloro-4-fluoro-5-(1,3,4,5,6,7-hexahydro-1,3-dioxo-2H-isoindol-2-yl)phenoxy]acetate
Brand name:	Resource Herbicide
Uses:	For selective weed control in field corn and soybeans
Pests controlled:	Weeds such as common ragweed, smooth pigweed, velvetleaf, and prickly side
Type of registration:	Conditional

Resource Herbicide is a liquid formulation containing 10.1% flumiclorac-pentyl ester. Resource Herbicide is a non-systemic contact chemical that inhibits protoporphyrinogen oxidase (PPO), causing rapid accumulation of protoporphyrin IX. Accumulated porphyrins are theorized to disrupt cell membranes including those of chloroplasts. Resource Herbicide is to be applied to field corn between the two leaf and the ten leaf stages when weeds are actively growing. Product labeling prohibits application of more than 6 fluid ounces (fl.oz.)/acre (A) of Resource Herbicide in a single broadcast application or more than a total of 8 fl.oz./A to field corn during a single

growing season. As a directed spray using drop nozzles, labeling prohibits applying more than a total of 8 fl.oz./A to field corn in a single application or during a single growing season.

SCIENTIFIC REVIEW

A. Chemistry

1. Product Chemistry**:** DPR evaluated the submitted chemistry studies for Resource Herbicide. The results are summarized in the following table.

Table I. Physical and Chemical Properties of Resource Herbicide

Properties	**Values**
Physical state	Liquid
Density (20^o)	1.3316 grams (g)/milliliter (ml) (Bulk)
PH (1% solution)	6.03 @ 25^oC
Solubility (water)	0.189 parts per million (ppm) (19^oC)
Vapor pressure	$<1 \times 10^{-7}$ mm Hg (22.4^oC)
Henry's law	$<2.95 \times 10^{-7}$ atm m^3 /mole
Stability	Stable at 54^oC for 14 days and in contact with steel pieces at 54^oC for 14 days. Stable on exposure to sunlight for 100 hours

Submitted product chemistry data support registration of Resource Herbicide.

2. Residues in Food and Animal Feed**:** An adequate residue analytical method was submitted. The U.S. EPA established tolerances at 40 Code of Federal Regulations (CFR) § 180.477 for residues of flumiclorac-pentyl, including all metabolites of flumiclorac-pentyl. When applied in accordance with the label directions flumiclorac-pentyl residues should not exceed the established 0.01 ppm tolerance for field corn grain, forage and stover.

3. Environmental Fate**:** The flumiclorac-pentyl environmental fate data included studies on soil hydrolysis, aqueous and soil photolysis, aerobic soil metabolism, aerobic and anaerobic aquatic metabolism, and field dissipation. The studies were found to be satisfactory. The registrant did not determine adsorption/desorption isotherms by the batch equilibrium method due to rapid hydrolysis in water, consequently K_d and K_{oc} values were not reported. A waiver request for the adsorption/desorption data requirement (specifically the K_d and K_{oc} calculations) on the basis of hydrolytic instability was submitted to the U.S. EPA.

   The reported water solubility, hydrolysis, aerobic and anaerobic soil metabolism half-lives do not exceed California groundwater criteria for mobility and persistence. The data suggest the flumiclorac-pentyl ester is not persistent or mobile.

   The submitted product, environmental fate, and residue chemistry data support registration of Resource Herbicide.

B. Toxicology

Valent U.S.A. Corporation submitted adequate toxicology studies to conduct complete toxicological evaluations of Resource Herbicide. DPR evaluated the submitted data to determine the potential for adverse health effects. The acute toxicity parameters for Resource Herbicide are summarized in the following table.

Table II. Acute Toxicity of Resource Herbicide

Type of Study	Acute Toxicity Values	Acute Toxicity Category
Acute Oral	LD_{50}>5000 mg/kg	IV
Acute Dermal	LD_{50}>2000 mg/kg	III
Acute inhalation*	LD_{50} 5.51 mg/l	IV
Primary eye irritation	N/A	IV
Primary dermal irritation*	N/A	II
Dermal Sensitization	N/A	Sensitizer
Signal word	N/A	WARNING

*The original toxicological evaluation report dated February 1, 2006, noted that the acute inhalation and primary dermal irritation studies for Resource Herbicide were unacceptable. In response to this conclusion, Valent U.S.A. Corporation submitted additional toxicological studies derived from an alternate formulation. The differences in the formulations were determined to be of minimal toxicological concerns. The additional acute inhalation and primary dermal irritation studies were acceptable.

DPR's evaluation of the acute toxicity studies indicates that the studies are adequate for a complete toxicological evaluation. The product label adequately identifies the potential acute toxicity hazards indicated by the data reviewed. The first aid statements and PPE are adequate for the indicated acute toxicity hazards.

DPR found the submitted toxicology studies for flumiclorac-pentyl sufficient to satisfy the data requirements of the Birth Defects Prevention Act (Food and Agricultural Code section 13121 et at). Possible adverse effects were noted in a mutagenicity study. DPR prioritizes pesticide active ingredients for risk assessment based on the nature of the potential adverse health effects, number of potential adverse effects, number of species affected, no effect levels (NOELs), potential for human exposure, use patterns and similar factors. Based on these criteria, pesticides with the greatest potential for health problems are placed in high priority, with other chemicals being in moderate or low priority. The purpose of the risk assessment would be to appraise the potential for flumiclorac-pentyl to cause adverse health effects in humans if exposed to the pesticide as a result of legal use. At this time, flumiclorac-pentyl has not been prioritized by DPR for risk assessment. Further toxicity information is available for flumiclorac-pentyl at DPR's public website in the Summary of Toxicology Data, available on DPR: http://www.cdpr.ca.gov/docs/toxsums/pdfs/5090.pdf.

C. Health & Safety

An evaluation of the medical management information on the Resource Herbicide label and the acute toxicity study results indicate that the product label bears all of the required statements and warnings regarding safety to handlers and other persons who may be exposed to the pesticide. The product label bears an adequate First Aid statement. In addition, the product label requires applicators and other handlers to wear coveralls worn over short-sleeved shirt and short pants, chemical resistant gloves and chemical resistant footwear plus socks, and protective eyewear. The instruction is also given to discard clothing and other absorbent materials that have been drenched or heavily contaminated with product concentrate.

D. Fish & Wildlife

The registrant submitted fish and wildlife toxicity studies, including studies on bluegill sunfish, rainbow trout, *Daphnia magna*, sheepshead minnow, mysid shrimp, oysters, bobwhite quail and mallard ducks. The submitted data are adequate to characterize the toxicity to wildlife and aquatic animals from an environmental exposure. Table III summarizes the results of these studies.

Table III. Summary of Fish & Wildlife Toxicity Values**

Test Animal	Type of Study	Acute Toxicity Value	Relative Toxicity
Bobwhite quail	Single acute oral dose	>2250 mg/kg (LD_{50})	Relatively non-toxic
Mallard duck	Feeding study (5 day)	>5620 mg/kg (LC_{50})	Relatively non-toxic
Bobwhite quail	Feeding study (5 day)	>5620 mg/kg (LC_{50})	Relatively non-toxic
Bobwhite quail	Reproduct study (21 wk)	500 ppm NOEC	Relatively non-toxic
Mallard duck	Reproduct study (24 wk)	250 ppm NOEC	Relatively non-toxic
Bluegill sunfish	Water exposure (96 hrs)	>13 mg a.i./l (LC_{50})	Slightly-toxic
Rainbow trout	Water exposure (96 hrs)	>1.1 mg a.i./l (LC_{50})	Moderately-toxic
Dapnia magna	Water exposure (48 hrs)	>38.0 mg a.i./l (LC_{50})	Slightly-toxic
Sheepshead minnow	Water exposure (96 hrs)	>24 mg a.i./l (LC_{50})	Slightly-toxic
Mysid shrimp	Water exposure (96 hrs)	>0.56 mg a.i./l (LC_{50})	Highly-toxic
Eastern oyster	Water exposure (96 hrs)	>1.8 mg a.i./l (LC_{50})	Moderately-toxic

**The test substance used for the studies was the technical active ingredient.

Valent U.S.A. Corporation submitted a request for a waiver of the requirement for life cycle testing with mysid shrimp. The justification provided was acceptable and the waiver for that specific aquatic requirement was granted.

The data indicate that penoxsulam is relatively non-toxic to birds, slightly-toxic to bluegill sunfish, sheepshead minnow, and *Dapnia magna,* moderately-toxic to rainbow trout and oysters, and highly-toxic to mysid shrimp. To mitigate the hazards to aquatic organisms the Resource Herbicide label contains the Environmental Hazards warning “This product is toxic to shrimp. Keep out of lakes, ponds or streams. Do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate”.

E. Efficacy & Phytotoxicity

Submitted efficacy and phytotoxicity studies indicate that Resource Herbicide provides effective control of many problem weeds in field corn production. Product labeling allows air and ground equipment application at up to 8 fluid ounces per acre per season.

For increased weed control, the addition of an approved spray adjuvant is required when Resource Herbicide is applied alone rather than tank mixed. The product labeling contains directions for jar testing to determine compatibility of adjuvants for use with Resource Herbicide. The label also contains instructions for tank mixing with twenty-eight approved herbicides and a claim for RAINFASTNESS, which states: "Resource is rainfast one hour after application. Applications should not be made if rain is expected within one hour of application or efficacy may be reduced." Data were not submitted to support the rainfast claim.

Submitted product efficacy and phytotoxicity data are adequate to support conditional registration of Resource Herbicide. The conditional registration is contingent upon the submission of the following efficacy data: 1) data supporting the one-hour rainfast claim; 2) data to support the label claims for control of ragweed and cocklebur; and 3) data derived from field testing performed under California conditions to confirm low drift potential from aerial application showing residue (deposition) versus injury to non-target crops.

ALTERNATIVES

Resource Herbicide is a liquid herbicide providing contact control of a broad range of weeds found in field corn production, including some difficult to control weeds such as common ragweed, smooth pigweed, velvetleaf, common lambsquarter and Palmer amaranth. It contains flumiclorac-pentyl, which is a phthalimide class herbicide. It is a non-systemic contact chemical that inhibits protoporphyrinogen oxidase (PPO). The protox inhibitors cause rapid accumulation of protoporphyrin IX. These accumulated prophyrins are theorized to disrupt cell membranes including those of chloroplasts, and chloroplasts are the food producers of plant cells. Resource Herbicide is effective as a tank mix with a wide variety of approved herbicides providing excellent weed control at low application rates and it has good corn tolerance. Key advantages of Resource Herbicide are its wide window of application with pending rain, excellent control of velvetleaf in corn, low application rates with good corn tolerance, and compatibility as a tank mix with many other herbicides.

CONCLUSION

DPR evaluated the product label and scientific data submitted to support the registration of Resource Herbicide. The label and data were found acceptable to support conditional registration. The acute health risks to human from exposure to flumiclorac-pentyl are minimal due to its low mammalian toxicity. The precautionary and first aid statements on the product label, and the recommended protective measures mitigate potential health risks to persons who may be exposed to these pesticides. If a risk assessment conducted by DPR determines that exposure to flumiclorac-pentyl may result in unacceptable margins of exposure, further restrictions will be placed on the use of flumiclorac-pentyl at that time. Submitted data indicate

that no significant adverse environmental impacts are expected to occur from the use of Resource Herbicide and that when used in accordance with label directions, the products will be effective for the intended use.

Conditional registration is recommended for Resource Herbicide, provided the registrant submits the following data: 1) data supporting the one-hour rainfast claim; 2) data to support the label claims for control of ragweed and cocklebur; and 3) data derived from field testing performed under California conditions to confirm low drift potential from aerial application showing residue (deposition) versus injury to non-target crops. The registrant has eighteen months to submit the data.